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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,728	11/03/2008	Patrick Lewis Blott	SMNPH.010APC	3322

20995 7590 01/28/2011  
KNOBBE MARTENS OLSON & BEAR LLP  
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EXAMINER
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HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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01/28/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/599,728	<b>Applicant(s)</b> BLOTT ET AL.	
	<b>Examiner</b> MELANIE J. HAND	<b>Art Unit</b> 3761	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/2/07, 11/3/08, 1/30/09</u> .                                | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statements***

2. The information disclosure statements (IDS) submitted on February 2, 2007, November 3, 2008, January 3, 2009 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

### ***Claim Objections***

3. Claim 7 is objected to because of the following informalities: the phrase "means for aspirate" contains a grammatical error. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "the first device" in line three. There is insufficient antecedent basis for this limitation in the claim.
6. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. It is the examiner's position that the precise scope of claim 10 is wholly unclear due to the construction of the claim. It is requested that claim 10 be amended to more clearly recite what is and is not encompassed by which structural elements or means.

7. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: all steps; no steps are recited in claim 14.

8.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (U.S. Patent Application Publication No. 2003/0021775).

With respect to **claim 1**: The examiner is invoking 35 U.S.C. 112, sixth paragraph, in the interpretation of claim 1, specifically with respect to the recited "means for supplying physiologically active agents to the wound", "means for providing simultaneous aspiration and irrigation of the wound." Freeman discloses an apparatus 80 for irrigating and cleansing wounds comprising the following: a) a fluid flow path, comprising a conformable wound dressing in the

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form of flexible engaging element 26, having a backing layer which is capable of forming a relatively fluid-tight closure over a wound and at least one inlet pipe 20 for connection to a fluid supply tube inasmuch as Freeman discloses that the inlet port 20 provides directional fluid motion for a protease irrigation solution, which passes through the wound-facing face, and at least one outlet pipe 22 for connection to a fluid offtake tube, which passes through the wound-facing face, the point at which the inlet pipe and the outlet pipe passes through the wound-facing face forming a relatively fluid-tight seal or closure over the wound; b) a fluid reservoir 10 connected by a fluid supply tube to an inlet pipe 20; c) at least one device, e.g. pump 18 and filter 32, for moving fluid through the wound dressing; characterized in that the apparatus 80 comprises the following: e) means for supplying physiologically active agents to the wound in the form of irrigation of the wound with a protease solution from reservoir 10; and f) means for providing simultaneous aspiration and irrigation of the wound in the form of a push-pull cannula 24, such that fluid may be supplied to fill the flowpath from the fluid reservoir 10 via the fluid supply tube while fluid is aspirated by a device via localized fluid forces through the fluid offtake tube 22. With regard to the limitations “optional means for supply flow regulation” and “optionally means for bleeding the flowpath”, since these features are recited as optional the examiner has not invoked 35 U.S.C. 112, sixth paragraph for the interpretation of these limitations.

With respect to **claim 2**: Claim 2 recites sufficient structure such that 35 U.S.C. 112, sixth paragraph, is not invoked. The means for supplying physiologically active agents to the wound disclosed by Freeman comprises the fluid reservoir 10 containing physiologically active components, namely a protease solution, necessarily in therapeutically active amounts to promote wound healing inasmuch as Freeman discloses that the solution collects and removes

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target cells from skin lesions to promote healing.

With respect to **claims 3,5**: The physiologically active agents for supply to the wound disclosed by Freeman are natural purified protein or recombinant-produced protein growth factors, e.g. plasmin. [0091]

With respect to **claim 4**: The physiologically active agents for supply to the wound disclosed by Freeman are materials that are beneficial in promoting wound healing by removing materials, namely target cells for the protease in the skin lesion.

With respect to **claim 6**: The physiologically active agents for supply to the wound disclosed by Freeman are local analgesics/anaesthetics.

With respect to **claims 7,9,11,12**: The limitation “means for providing simultaneous...often comprises” is treated as an optional limitation with regard to the recited first device in combination with at least one of a second device that is one or more of the listed items in claim 7. The means for providing simultaneous aspiration and irrigation of the wound comprises a push-pull cannula 24, such that fluid may be supplied to fill the flowpath from the fluid reservoir 10 via the fluid supply tube (first device, considered herein to be a fixed throughput device) while fluid is aspirated by a device via localized fluid forces through the fluid offtake tube 22 (second device).

With respect to **claim 8**: The aspirate in the fluid offtake tube 22 disclosed by Freeman downstream of the wound dressing is aspirated into a collection vessel 30, and the first device,

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filter 32, acts on fluid from the collection vessel 30. [0076]

With respect to **claims 10,13**: The second device, offtake tube 22 disclosed by Freeman, is a variable-throughput device, wherein the throughput is associated with the rate of delivery of protease solution which is restricted by applicator 24. [0074] The means for providing simultaneous aspiration and irrigation of the wound, the push-pull cannula 24, accomplishes the aspiration and irrigation alone and thus the means for providing simultaneous aspiration and irrigation of the wound does not comprise other means for aspirate flow regulation, connected to a fluid offtake tube and/or other means for supply flow regulation, connected to a fluid supply tube.

With respect to **claim 14**: Freeman discloses a method of treating wounds to promote wound healing using an apparatus 80 meeting all of the structural and functional limitations of claim 1. [0073],[0074]

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/  
Primary Examiner, Art Unit 3761